K091137

510(K) SUMMARY

APR 22 2009

5.1. APPLICANT INFORMATION

Submitted by:	St. Jude Medical
	6500 Wedgwood Rd. N.
	Maple Grove, MN 55311
Contact Person:	Linh Pham
Telephone:	763-383-2586
Fax:	763-383-2559
Date Prepared:	10 April, 2009

5.2. DEVICE INFORMATION

Classification Name:	Introducer, Catheter
Common Name:	Hemostasis Introducer
Trade Name:	Ultimum/Engage/Engage TR
Classification:	Class II per 21 CFR 870.1340
Product Code:	DBY

Ultimum and Engage are the same devices (intended use, function and specifications, and device materials). SJM reserves the right to modify the trade name of the Ultimum/Engage device in the future; as a result, the name, Engage Introducer (Engage), will be referred to for the remainder of this submission.

5.3. DEVICE DESCRIPTION

The Engage device consists of an introducer sheath with hemostasis valve and sideport for 3-way stopcock, hub, dilator, and guidewire. At the end of the sheath is a snap fit hub that is equipped with a hemostasis valve and sideport containing tubing ending with a 3-way stopcock valve. The 3-way stopcock is provided for air aspiration, fluid infusion, blood sampling and pressure monitoring. The dilator lumen is designed to provide close fit to appropriately sized guidewires by incorporating a tapered distal tip.

To further assist physicians on the application of the Ultimum/Engage device, SJM is providing physicians with more clarity in the device's indications for use.

5.4. INTENDED USE

The introduction of angiographic catheters, closed end catheters, balloon catheters, and electrodes into a blood vessel (including but not limited to femoral, radial, and brachial access) where minimizing blood loss is essential.

5.5. TEST SUMMARY

This submission is for indication clarification; there have been no device changes and subsequently, no additional device testing was required.

5.6. PREDICATE DEVICE

The predicate devices are provided below:

Product Name	**510k #**
Ultimum Hemostasis Introducer (St. Jude Medical)	K001346 (cleared 05/24/2000)
GlideSheath (Terumo Corporation)	K082644 (cleared 09/18/2008)

5.7. SUBSTANTIAL EQUIVALENCE

The Engage Introducer covered by this submission is substantially equivalent to the previously cleared St. Jude Medical's Ultimum Hemostasis Introducer—*K001346-05/24/2000* and Terumo's GlideSheath—*K082644-09/18/2008*. Differences between devices do not raise any issues of safety or effectiveness.

5.8. CONCLUSION

The Engage Introducer in this submission has the same intended use, principles of operation, and technological characteristics as the Ultimum Hemostasis Introducer (K001346), and it has similar sub-indications for use and principles of operations as the Terumo GlideSheath (K082644). The Engage is submitted to provide further clarification to the physicians regarding the indications for use of Ultimum in procedures requiring vessel access, including but not limited to femoral, radial, and brachial approach.

As a result, the differences between this device and its predicate device do not raise new questions of safety or efficacy. Therefore, the Engage Introducer is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2009

St. Jude Medical
c/o Mark Job, Reviewer
Regulatory Technology Services
1394 25th Street NW
Buffalo, MN 55313

Re: K091137
Trade/Device Name: Ultimum/Engage/Engage TR Hemostasis Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 17, 2009
Received: April 20, 2009

Dear Mr. Job:

This letter corrects our substantially equivalent letter of April 22, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your

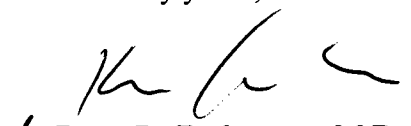
device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director, Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Device Name: Ultimum/Engage/Engage TR

Indications for Use:

The introduction of angiographic catheters, closed end catheters, balloon catheters, and electrodes into a blood vessel (including but not limited to femoral, radial, and brachial access) where minimizing blood loss is essential.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K091372